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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,074

11/19/2003

Richard J. Davies

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530 7590 11/17/2006

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/717,074

Applicant(s)

DAVIES, RICHARD J.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 13-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/6/05; 3/6/06</u> | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

1. Newly submitted claims 1-5 and 37-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly amended Claim 1 discloses using the apparatus on an epithelial region of tissue, similar to withdrawn Claims 13-21.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-5 and 37-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al. (5,345,935).

Hirsch et al. teach an apparatus for determining the condition of a region of tissue. The apparatus includes a cup (10, 110) having an interior (12, 113) and first and second openings. An electrode (33) is disposed within the interior. A source of suction (24, 42) is connected to the second opening (22, 122). When the first opening is placed

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over a region of tissue and suction is applied to the second opening, an electrical connection is made between the region of tissue to be examined and the electrode. A flange (19, 119) surrounds the first opening. The source of suction is a syringe (see Figs. 9-11) or aspirator (24). A measuring device (63) communicates with the electrode to determine an electrical signal from the electrode and a display device may display the electrical signal from the electrode. Regarding claims 8 and 9, the Examiner respectfully submits that the characteristics of the tissue being examined by the device have no effect on the structure of the claimed apparatus. Therefore, since the apparatus of Hirsch et al. is capable of examining such tissue, the Hirsch et al. apparatus is deemed to read on claims 8 and 9.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (5,345,935) in view of Dempsey et al. (5,417,222).

Hirsch et al., as described above, teach all of the limitations of the claims except that there are wireless connections between the measuring unit and the electrode and between the measuring device and the display device.

Dempsey et al. teach the desirability of providing wireless connections between electrodes, processors and displays in order to allow monitoring of a patient wearing the electrode apparatus while enabling freedom of movement the patient wearing the apparatus at least within selected areas of the institution, where the patient is not encumbered by wires or conductive leads.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide wireless connections between the electrodes, measuring unit and display of an apparatus similar to that of Hirsch et al. in light of the teachings of Dempsey et al, in order to allow monitoring of a patient wearing the electrode apparatus while enabling freedom of movement the patient wearing the apparatus at least within selected areas of the institution, where the patient is not encumbered by wires or conductive leads.

### ***Response to Arguments***

6. Applicant's arguments filed September 6, 2006 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., determining transepithelial electropotential and/or impedance characteristics in order to diagnose pre-malignancy or cancer and introducing pharmacological agents to challenge the transepithelial tissue) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification

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are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### **Conclusion**

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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